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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,539	02/26/2002	Wenda Carlyle	PA872	9853

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EXAMINER	
FISHER, ABIGAIL L	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
04/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/085,539	CARLYLE ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 15 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-7,9,11 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-7,9,11 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 18 2008 has been entered.

Receipt of Amendments/Remarks filed on December 18 2008 is acknowledged. Claims 2-5, 8, 10 and 12-26 were/stand cancelled. Claims 1 and 6 were amended. Claims 1, 6-7, 9, 11 and 27 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Interpretation

Claim 1 and the claims that depend from claim 1 contain the transitional language "consisting essentially of". For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." If an applicant contends that

additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *PPG Industries Inc. V Guardian Industries Corp.* 48 USPQ2d 1351 (Fed. Cir. 1998) and *In re De Lajarte* 337 F.2d 870, 143 USPQ 256 (CCPA 1964) **See MPEP 2111.03.**

The instant specification does not define the term "consisting essentially of" in a manner that would allow one skilled in the art to determine what basic and novel characteristics are being materially affected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6-7, 9, 11 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US Patent No. 5464650, cited on PTO Form 1449) in view of Su et al. (J. Clinical Investigation, 1999) as evidenced by Aviram et al. (WO 99/48529, cited on PTO Form 1449).

Applicant Claims

Applicant claims a site-specific drug delivery medical device consisting essentially of rosiglitazone and at least one biocompatible polymer. The biocompatible polymer is poycaprolactone. The device is a vascular or biliary stent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Berg et al. is directed to an intravascular stent. It is taught that it is known in the art restinosis is a known problem with stents (column 1, lines 44-46). One method of

overcoming restinosis is to provide a therapeutic substance that reduces the instance of restinosis (column 1, lines 58-67). The invention allows for the sustained release of the drug to vascular tissue (column 2, lines 20-22). Many different active agents can be utilized. One particular example is anti-inflammatory agents (column 5, lines 19-40). Example 3 is directed to a solution comprising only dexamethasone and polycaprolactone in acetone. This solution was applied to a stent to coat the stent.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Berg et al. does not specify that the therapeutic substance is rosiglitazone. However, this deficiency is cured by Su et al.

Su et al. indicates that PPARγ agonists reduce colonic inflammation. The results indicate that troglitazone or BRL 49653 (rosiglitazone) exhibit a highly significant anti-inflammatory effect (page 33, last paragraph).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to have combined the teachings of Berg et al. and Su et al. and utilize rosiglitazone as the therapeutic substance. One of ordinary skill in the art would have been motivated to select rosiglitazone as Berg et al indicates that anti-inflammatory agents are suitable therapeutic agents to be utilized in the stent coating and Su et al. indicates that rosiglitazone exhibits significant anti-inflammatory effect. Furthermore, the selection of

a specific drug is considered prima facie obvious depending on the desired condition/symptoms to be treated.

One of ordinary skill in the art would have a reasonable expectation of success because as evidenced by Aviram, rosiglitazone is known to be useful for treating restenosis (abstract).

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that (1) SU is not analogous art so there is no motivation to combine. Applicants argue that (2) the broad disclosure of Berg does not teach or suggest utilizing PPAR-γ inhibitors as the anti-inflammatories and certainly does not teach or suggest rosiglitazone. Applicants argue that the mere fact that Berg suggests the class of anti-inflammatories does not mean that each and every member of that class will be effective in delivery from a stent to the blood vessel. Applicants argue that (3) there is no expectation of success in the combination of Berg et al. and Su et al.

Applicants' arguments filed December 18 2008 have been fully considered but they are not persuasive.

Regarding applicant's first argument, Berg et al is directed to the instantly claimed invention in so much as it is directed to a method for making an intravascular

stent by applying to the body of a stent a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent. The only difference between the instantly claimed invention and that taught in Berg et al. is that the instant invention claims a specific drug, which is rosiglitazone. Berg et al. clearly teaches that the therapeutic substance that can be applied to the stent includes anti-inflammatories. The examiner maintains that it would have been obvious to one of ordinary skill in the art to look to the pharmaceutical literature for specific anti-inflammatory drugs. Su clearly teaches that rosiglitazone is a known anti-inflammatory drug. Therefore, it would have been obvious to one of ordinary skill in the art to utilize a specific anti-inflammatory in the invention of Berg et al. as Berg et al. specifically teach that this is one type of drug that can be utilized with the stent. The teachings of Su are solely utilized to show that rosiglitazone is a known anti-inflammatory agent in the art. The only difference between the instant invention and Berg et al. is the selection of a specific drug and the selection of a specific drug is considered prima facie obvious depending on the desired condition/symptoms to be treated. Since it is deemed that selection of a specific drug is considered prima facie obvious, Berg and Su are analogous art because one of ordinary skill in the art would have been motivated to look elsewhere in the pharmaceutical literature for the names of other known anti-inflammatory agents.

Regarding applicants' second argument, the examiner agrees that Berg does not teach utilizing PPAR-γ inhibitors and rosiglitazone but that is why Su is relied upon. Berg generally teaches that the drugs that can be incorporated include anti-

inflammatory agents. Su teaches that rosiglitazone exhibits a highly significant anti-inflammatory effect. Therefore, the examiner argues that a *prima facie* case of obviousness has been established as one of ordinary skill in the art would have been motivated to utilize rosiglitazone as it is taught in the art as a compound that exhibits significant anti-inflammatory effect and Berg teaches that anti-inflammatories can be incorporated. One of ordinary skill in the art would have been motivated to utilize different anti-inflammatories in order to determine which anti-inflammatories would be useful in the device taught by Berg.

The instant invention is directed to a stent with a polymeric coating comprising a specific anti-inflammatory. The prior art teaches a stent with a polymeric coating comprising active agent. One specific class of active agents taught is anti-inflammatories. The prior art also recognizes rosiglitazone as an anti-inflammatory. Therefore, all of the claimed elements where known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. **Note: MPEP 2141 [R-6]** *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007).

Regarding applicants' third argument, since rosiglitazone is known in the art to be useful in treating restinosis as evidenced by Aviram, one of ordinary skill in the art would have a reasonable expectation of success.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-7, 9, 11 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 11383262. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a site-specific drug delivery medical device consisting essentially of rosiglitazone and at least one biocompatible polymer. The biocompatible polymer is poycaprolactone. The device is a vascular or biliary stent

Copending '262 claims a biodegradable polymer for coating an implantable medical device comprising a first monomer and optionally a second monomer wherein

said first monomer comprises a modified caprolactone. Medical devices claimed include vascular stents. The polymer further comprises a drug.

The difference between the instant application and copending '262 is that the instant application claims a specific type of drug.

The relationship between the instant application and copending '262 is a genus-species relationship. Rosiglitazone is a particular type of drug. Therefore, both the instant application and copending '262 are directed to similar subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 6-7, 9, 11 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-18 of copending Application No. 11619122 in view of Berg et al. and in further view of Su et al.. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a site-specific drug delivery medical device consisting essentially of rosiglitazone and at least one biocompatible polymer. The biocompatible polymer is poycaprolactone. The device is a vascular or biliary stent

Copending '122 claims a coating for an implantable medical device comprising a biocompatible amphiphilic polymer comprising a polyester and a polyether backbone. The monomers are selected from a group that includes caprolactone. The medical device as claimed includes vascular stents.

Copending '122 does not claim that the coating comprises rosiglitazone. However, this deficiency is cured by Berg et al. and Su.

Berg et al. is directed to intravascular stents. The inclusion of a polymer in contact with a drug on the stent allows for the drug to be retained on the stent and allows for control of the drug release (abstract). It is disclosed that stents are utilized to provide therapeutic substances to the vascular wall (column 1, line 58-59). Therapeutic substances that can be delivered include anti-inflammatory agents (column 5, line 28).

Su et al. indicates that PPARγ agonists reduce colonic inflammation. The results indicate that troglitazone or BRL 49653 (rosiglitazone) exhibit a highly significant anti-inflammatory effect (page 33, last paragraph).

It would have been obvious to one of ordinary skill in the art to combine Copending '122, Berg et al. and Su et al. and include a rosiglitazone in the coating of Copending '122. One of ordinary skill in the art would have been motivated to include a drug because Copending '122 is directed to coatings for stents and Berg et al. indicates that stents are utilized to provide therapeutic substances to the vascular wall. One of ordinary skill in the art would have been motivated to select rosiglitazone as the therapeutic substance because Berg et al. indicates that therapeutic substance that can be delivered include anti-inflammatory agents and Su et al. indicates that rosiglitazone exhibits significant anti-inflammatory effects. Further more, the selection of a specify drug is considered prima facie obvious depending on t he desired condition/symptoms to be treated.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed December 18 2008 are acknowledged. The rejections are maintained since applicant has not made any substantive arguments traversing the rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616